

**REMARKS**

Claims 1-20 and 35-37 are currently pending in this application, as amended. Claims 21-34 were previously canceled for being directed to a non-elected invention. Claim 2 has been rewritten in independent form including all of the features of the base claim. Claims 1 and 12 have been amended to more particularly point out and distinctly claim the invention. Support for the claim amendments can be found in, among other places, the originally submitted Specification at paragraphs [0046]-[0050]; paragraphs [0054]-[0055]; and Figs. 1, 3, 7 and 9. New claims 35-37 have been added to depend from allowed claim 10. Support for the new claims can be found in the original Specification at paragraphs [0060] and [0062] and in Figs. 1 and 6A-6D, among other places. Accordingly, no new matter has been added.

***Claim Rejections Under 35 U.S.C. § 103(a)***

**Rejection of Claims 1 and 4-9**

Claims 1 and 4-9 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,398,678 (“Gamow”) in view of U.S. Patent No. 2,998,009 (“Holm *et al.*,” hereinafter, “Holm”) and U.S. Patent No. 1,224,180 (“Lake”).

Withdrawal of the rejections of claims 1 and 4-9 is respectfully requested in view of the foregoing amendments and for at least the following reasons.

**Present Invention**

The present invention is directed to, among other things, a hyperbaric oxygen therapy system including a pressure vessel containing a gas, an oxygen concentration measurement apparatus for monitoring a concentration of oxygen in the gas, an environmental control apparatus for controlling the temperature of the gas in the vessel and a pressure/ventilation control apparatus for controlling the pressure of the gas in the vessel. The vessel is capable of accommodating a patient. The oxygen concentration measurement apparatus includes an oxygen analyzer coupled to one of an electronic and an electro-chemical oxygen concentration sensing unit that provides an electrical output signal representative of the

concentration of oxygen in the gas to the oxygen analyzer. The oxygen analyzer displays an indication of oxygen concentration based on the electrical output signal.

The present invention is also directed to, among other things, a hyperbaric oxygen therapy system having a pressure vessel containing a gas and an environmental control apparatus. The environmental control apparatus includes a scrubber, a heat exchanger and a blower located within the pressure vessel, each of which is in fluid communication with the gas. The environmental control apparatus also includes a heat pump external to the pressure chamber, in fluid communication with the heat exchanger by a conduit having an exchange fluid therein; a temperature sensor in fluid communication with the gas in the vessel which provides an electrical output signal representative of a temperature of the gas; and a temperature controller having an adjustable set point which receives the electrical output signal of the temperature sensor and provides a control signal to the heat pump for adjusting the temperature of the exchange fluid to thereby maintain the temperature of the gas within a predetermined range of the set point. The temperature controller is configured to display a representation of the temperature sensed by the temperature sensor and the adjustable set point.

#### Gamow

Gamow discloses a portable hyperbaric enclosure (“mountain bubble”) with a means for maintaining a gas pressure of 10 pounds per square inch (PSI) including a blower and a gas (oxygen) tank. The portable hyperbaric enclosure is used in conjunction with an oxygen source delivered by a pressure regulator and with a carbon dioxide scrubber so as to maintain a pressurized environment with an appropriate level of breathable oxygen for a person inside the enclosure.

#### Holm

Holm discloses an electro-mechanically regulated apparatus (i.e., response element to magnet to induced signal to valve), primarily for air that is being continually re-breathed, that “automatically maintains oxygen content” of the air (breathable gas) such as for deep-sea diving. The device conducts a current of gas that has been breathed by a human being past a sensor that is “responsive” to a percentage of oxygen in the medium in order to prevent

either an oversupply or an under supply of oxygen. The sensor includes a rotatable or swingable body that is influenced to rotate by the paramagnetic properties of different concentrations of nitrogen and oxygen in a standard gas versus a sample gas. When the rotatable body moves between pole pieces of a fixed magnet, an electrical current is induced which is then amplified and used to control a normally open oxygen control valve. (see col. 3, lines 20-72).

While the sensor of Holm operates off of paramagnetic properties of the sensed gas, the system uses mechanical rotation or swinging of a body to move between poles pieces of a fixed magnet which creates an electric signal coupled directly to a control valve.

#### Lake

Lake discloses an electro-mechanically (i.e., thermostatically) regulated apparatus for controlling gas temperature in a compression/vacuum chamber designed for humans. Lake discloses a thermostat that controls a solenoid which directs or diverts a flow of air through a heat exchanger to directly control the temperature of the air in a chamber. Lake also has an air regulator for controlling pressure and a source of purified air. While a thermostat electromechanically responds to temperature by opening and closing bi-metallic contacts, a thermostat does not output an electrical signal representative of a temperature sensed (i.e., a thermostat merely opens or closes at a particular setpoint) and does not display an indication of temperature or of setpoint.

#### Claim 1

Claim 1, as amended, recites, *inter alia*:

an oxygen concentration measurement apparatus for monitoring a concentration of oxygen in the gas, the oxygen concentration measurement apparatus including an oxygen analyzer coupled to one of an electronic and an electro-chemical oxygen concentration sensing unit that provides an electrical output signal representative of the concentration of oxygen in the gas to the oxygen analyzer, the oxygen analyzer displaying an indication of oxygen concentration based on the electrical output signal ...

Gamow, Holm and Lake, taken alone or in combination, fail to disclose or suggest a hyperbaric oxygen therapy system having an oxygen concentration measurement apparatus for monitoring a concentration of oxygen in the gas including an oxygen analyzer coupled to one of an electronic and an electro-chemical oxygen concentration sensing unit that provides an electrical output signal representative of the concentration of oxygen in the gas to the oxygen analyzer and that the oxygen analyzer displays an indication of oxygen concentration.

Gamow merely discloses a portable hyperbaric enclosure (“mountain bubble”) with a means for maintaining a gas pressure of 10 PSI including a blower and a gas (oxygen) tank, used in conjunction with a pressure regulator and a carbon dioxide scrubber.

Holm merely discloses an electro-mechanically regulated apparatus (i.e., response element to magnet to induced signal to valve), primarily for air that is being continually re-breathed, that “automatically maintains oxygen content” of the air (breathable gas). While the sensor of Holm operates off of paramagnetic properties of the sensed gas, the system uses mechanical rotation or swinging of a body to move between poles pieces of a fixed magnet which creates an electric signal coupled directly to a control valve. Thus, Holm fails to disclose or suggest either an electronic or electro-chemical sensor the provides an electrical signal proportional to an oxygen concentration analyzer and that that the oxygen concentration analyzer displays an indication of oxygen concentration.

Lake fails to compensate for the deficiencies of Gamow and Holm. Lake discloses an electro-mechanically (i.e., thermostatically) regulated apparatus for controlling gas temperature in a compression/vacuum chamber designed for humans. Lake has an air regulator for controlling pressure and a source of purified air, but lacks an oxygen concentration analyzer.

To establish *prima facie* obviousness of a claimed invention, all the claimed limitations must be taught or suggested by the prior art. MPEP § 2143.03. Thus, all the claimed elements and features of claim 1 are not disclosed by the modified Gamow device. Furthermore, even if it were proper to modify Gamow in view of Holm and Lake, the modified Gamow system would still not include an oxygen concentration measurement apparatus for monitoring a concentration of oxygen in the gas including an oxygen analyzer coupled to one of an electronic and an electro-chemical oxygen concentration sensing unit that provides an electrical output

signal representative of the concentration of oxygen in the gas to the oxygen analyzer and that the oxygen analyzer displays an indication of oxygen concentration, as recited in claim 1.

Applicants therefore respectfully submit that claim 1 is not obvious under 35 U.S.C. § 103(a) in view of the combination of Gamow, Holm and Lake. Claims 4-9 are dependent upon independent claim 1 and are therefore not obvious under 35 U.S.C. § 103(a) in view of the combination of Gamow, Holm and Lake for the same reasons mentioned with respect to claim 1 and because they each recite additional patentable elements and/or features. Accordingly, Applicants respectfully request that the rejection of independent claim 1 and dependent claims 4-9 under 35 U.S.C. § 103(a) be withdrawn.

#### Rejection of Claims 12-15

Claims 12-15 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Gamow in view of Lake.

Withdrawal of the rejections of claims 12-15 is respectfully requested in view of the foregoing amendments and for at least the following reasons.

#### Claim 12

Claim 12, as amended, recites, *inter alia*:

a temperature sensor in fluid communication with the gas in the vessel which provides an electrical output signal representative of a temperature of the gas; and

a temperature controller having an adjustable set point which receives the electrical output signal of the temperature sensor and provides a control signal to the heat pump for adjusting the temperature of the exchange fluid to thereby maintain the temperature of the gas within a predetermined range of the set point, the temperature controller being configured to display a representation of the temperature sensed by the temperature sensor and the adjustable set point.

Gamow and Lake, taken alone or in combination, fail to disclose or suggest a hyperbaric oxygen therapy system having an environmental control apparatus including a temperature sensor in fluid communication with a gas in a vessel which provides an electrical

output signal representative of a temperature of the gas and a temperature controller having an adjustable set point which receives the electrical output signal of the temperature sensor and provides a control signal to a heat pump for adjusting the temperature of the exchange fluid to thereby maintain the temperature of the gas within a predetermined range of the set point where the temperature controller is configured to display a representation of the temperature sensed by the temperature sensor and the adjustable set point.

Gamow discloses a portable hyperbaric enclosure with a means for maintaining a gas pressure of 10 PSI including a blower and a gas (oxygen) tank. But, Gamow lacks any means of environmental temperature control. Lake discloses a thermostat that controls a solenoid which directs or diverts a flow of air through a heat exchanger to directly control the temperature of the air in a chamber. While a thermostat electromechanically responds to temperature by opening and closing bi-metallic contacts, a thermostat does not output an electrical signal representative of a temperature sensed. Furthermore, a thermostat does not display a representation of such a sensed temperature or display an adjustable set point.

Thus, all the claimed elements and features of claim 12 are not disclosed by the modified Gamow device. Applicants therefore respectfully submit that claim 12 is not obvious under 35 U.S.C. § 103(a) in view of the combination of Gamow and Lake. Claims 13-15 are dependent upon independent claim 12 and are therefore not obvious under 35 U.S.C. § 103(a) in view of the combination of Gamow and Lake for the same reasons mentioned with respect to claim 12 and because they each recite additional patentable elements and/or features. Accordingly, Applicants respectfully request that the rejection of independent claim 12 and dependent claims 13-15 under 35 U.S.C. § 103(a) be withdrawn.

***Allowable Subject Matter***

The Examiner has stated that claims 10-11 and 16-20 are allowed.

The Examiner has further stated that claims 2-3 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicants have rewritten claim 2 in independent form including all of the features of the base claim (original claim 1). Claim 3 remains dependent upon amended independent claim 2. Accordingly, Applicants respectfully request that the objection to claims 2-3 be withdrawn.

Applicants appreciate the Examiner's willingness to allow claims 2-3, 10-11 and 16-20, but it is respectfully submitted that claims 1, 4-9 and 12-15 are also allowable.

*New Claims*

New claims 35-37 have been added to depend from allowed claim 10, and are allowable because of their dependence upon allowed claim 10 and because they recite additional patentable features.

Support for the new claims can be found in the original Specification at paragraphs [0060] and [0062] and in Figs. 1 and 6A-6D, among other places. Accordingly, no new matter has been added by the addition of dependent claims 35-37.

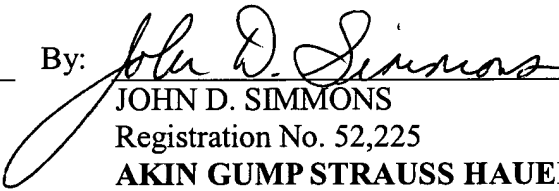
**CONCLUSION**

It is respectfully submitted that the present application, including claims 1-20 and 35-37, is in condition for allowance, and such action is respectfully requested.

Respectfully submitted,

WILLIAM T. GURNEÉ *et al.*

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By:   
JOHN D. SIMMONS  
Registration No. 52,225  
**AKIN GUMP STRAUSS HAUER & FELD LLP**  
One Commerce Square  
2005 Market Street, Suite 2200  
Philadelphia, PA 19103-7013  
Telephone: 215-965-1200  
**Direct Dial: 215-965-1268**  
Facsimile: 215-965-1210  
E-Mail: jsimmons@akingump.com

JDS/MGB